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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,428	08/04/2006	Hiroshi Nagai	SHOBA6.001APC	9228

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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01/26/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/588,428	Applicant(s) NAGAI ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/11</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims and Previous Objections/Rejections Status

1. Claims 1,2 and 5-7 are pending in the application.
2. The rejection of claims 1,2 and 5-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment to the claims.
3. The rejection of claims 1,2 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and Shirahata et al. (Animal Cell Technology: basic & applied aspects: proceedings of the Thirteenth Annual Meeting of the Japanese Association for Animal Cell Technology (JAACT), Fukuoka-Karatsu, Springer, November 16-21, 2000, Vol 12) and in further view of Iwasaki et al. (US 7,014,876B2) is maintained.

Information Disclosure Statement

4. The information disclosure statement filed 7/11/11 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments

5. Applicant's arguments filed 11/4/11 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1,2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and Shirahata et al. (Animal Cell Technology: basic & applied aspects: proceedings of the Thirteenth Annual Meeting of the Japanese Association for Animal Cell Technology (JAACT), Fukuoka-Karatsu, Springer, November 16-21, 2000, Vol 12) and in further view of Iwasaki et al. (US 7,014,876B2) as stated in the office action mailed 7/5/11.

8. Applicant asserts that claims 1,2 and 5-7 are patentable at least because Applicants have demonstrated superior unexpected properties that could not have been predicted by one having ordinary skill in the art even in view of the cited references. These results are reported both in the specification and in the Rule 132 Declaration of Mari Yamamoto, one of the inventors of the present application that was submitted with Applicants response of January 14, 2011. The data provided in the Declaration show that Benifuuki tea (Test Beverage 1), which is one of the teas recited in present claims 1

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and 6, contains a significant amount of catechins, including methylated catechins (6.8 mg/100 ml beverage), while Yabukita tea (Test Beverage 2), which is not recited in the present claims, contains catechins, but no methyl catechins. In addition, the barley beverage (Test Beverage 3), which contains no detectable levels of catechins, whether methylated or not, was included as a control. (Declaration, paragraphs 6 and 8, and Tables 1 and 3). When the different beverages were tested for their ability to lower blood triglyceride (BTG) levels, Test Beverage 1 exhibited an unexpectedly large level of reduction in BTG levels (Declaration, paragraph 9 and Table 4). Importantly, the average triglyceride level in the group of test subjects was significantly lowered after six weeks of consuming Test Beverage 1 (the Benifuki green tea), whereas triglyceride levels in test subjects were not significantly lowered after six weeks of consuming the Test Beverages 2 or 3 (Yabukita green tea or barley tea) (Id.). These results illustrate that the beverages containing methylated catechins have remarkable and unexpected effects of reducing triglyceride levels compared to beverages not containing methylated catechins. In particular, the green tea beverage obtained from a strain of tea containing significant amounts of catechins, but no methyl catechins (Yabukita green tea), performed no better in reducing BTG than the barley tea, which has no catechins at all. Thus, only the green tea beverage containing a significant level of methyl catechins had a significant effect on triglyceride levels. (Declaration, paragraph 10).

9. The extremely high range of standard deviations across all samples, found in Table 4 (Declaration filed 1/17/11, p4), results in significant overlap in triglyceride levels

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and makes them ambiguous. The overlapping of the size of the standard deviations negates the applicant's claim of unexpected results.

10. Further, Zeyuan et al. teaches of the method of reducing and examining blood triglyceride levels in a subject via the administration of green tea (unfermented) extracts/functional beverages. The blood triglycerides were significantly reduced by 33.3% with green tea and green tea extracts. Therefore, the significant effect on triglyceride levels via the administration of green teas is not unexpected.

11. Suzuki et al. teaches that the O-methylated catechin derivative EGCG3"Me from tea leaves of Benihomare cultivar (green unfermented tea) and (-)-epigallocatechin-3-O-gallate (EGCG) extracts show analogous inhibition of type I and IV allergy upon oral administered to mice.

12. Zeyuan et al. teaches that the constituents of green tea extracts comprising catechins reduce blood triglyceride levels and therefore at the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize/try the green tea Benihomare cultivar (comprising (-)- epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me)) of Suzuki et al. for the green tea extracts/functional beverages for the method of reducing blood triglyceride levels of Zeyuan et al. as Benihomare has advantageous properties, such as show analogous inhibition of type I and IV allergy.

13. Suzuki et al. teaches that EGCG and EGCG3"Me have analogous properties and therefore, it is obvious to those skilled in the art to make known substitutions on compounds (e.g. green tea) that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further

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manipulate a compound to generate the desired effect, such as reducing blood triglyceride levels.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 7-4 M, 7-4 T, 6 Th, 7-4 F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa Perreira/

Examiner, Art Unit 1618

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618